

CLAIMS

What is claimed is:

1. A lateral flow assay device for quantitative detection of target analytes in a sample,
 - 2 said device comprising:
 - an assay support member having a first end and a second end;
 - 4 a sample receiving element at one end of said support member for introduction of the sample to be analyzed to said device; and
 - 6 an immunoassay test strip comprising:
 - a porous analytical membrane removably mounted adjacent to and generally parallel
 - 8 with said support member, said analytical membrane having a first end and a second end;
 - at least one capture region in said analytical membrane intermediate said first and
 - 10 second ends thereof, said at least one capture region being configured to capture labeled
 - analytes moving from said first end of said analytical membrane toward said second end of
 - 12 said analytical membrane; and
 - 14 a backing member between said analytical membrane and said support member to facilitate removal of said analytical membrane from said support member for reading the assay and for archiving said test strip.
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 2. The device recited in claim 1, and further comprising a protective membrane covering
 - 2 said analytical membrane on the side opposite to said support member, said protective membrane being optically non-transparent.

3. The device recited in claim 2, wherein said protective membrane is formed integrally
6 with said porous membrane.

8 4. The device recited in claim 2, wherein said protective membrane is formed pursuant
to a surface treatment of said porous membrane.

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12 5. The device recited in claim 1, and further comprising a control region in said porous
membrane for collection of magnetic conjugates that have passed the capture region to show that
said test strip has been used.

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16 6. The device recited in claim 2, and further comprising at least one magnetic
calibration line printed on said protective membrane.

18 7. The device recited in claim 2, wherein said protective membrane is formed of
material selected from the group consisting of plastic, glass and paper.

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22 8. The device recited in claim 1, and further comprising superparamagnetic conjugate
particles in said sample receiving element, said particles being configured to bind with target
analytes in the sample.

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9. A lateral flow assay device for quantitative detection of target analytes in a sample,
2 said device comprising:
an assay support member having a first end and a second end;

4 a sample receiving element near one end of said support member for introduction of the
sample to be analyzed to said device; and

6 an immunoassay test strip comprising:

 a porous analytical membrane removably mounted adjacent to and generally parallel
8 with said support member, said analytical membrane having a first end and a second end;
 superparamagnetic conjugate particles in said sample receiving element configured
10 to bind with the target analytes in the sample;

12 a capture region in said analytical membrane intermediate to said first and second
ends thereof, said capture region being configured to capture labeled analytes moving from
said first end of said analytical membrane toward said second end of said analytical
14 membrane; and

16 a backing member between said analytical membrane and said support member to
facilitate removal of said analytical membrane from said support member for reading the
assay and for archiving said test strip.

10. The device recited in claim 9, and further comprising a protective membrane covering
2 said analytical membrane on the side opposite to said support member, said protective membrane
being optically non-transparent.

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11. The device recited in claim 10, wherein said protective membrane is formed
6 integrally with said porous membrane.

8 12. An analytical immunoassay apparatus for quantitative detection of target analytes

in a sample, said apparatus comprising:

- 10 an assay support member having a first end and a second end;
- a sample receiving element near one end of said support member for introduction of
- 12 the sample to be analyzed to said apparatus;
- an immunoassay test strip comprising:
- 14 a porous analytical membrane removably mounted adjacent to and generally parallel
- with said support member, said analytical membrane having a first end and a second end;
- 16 superparamagnetic conjugate particles in said sample receiving element configured
- to bind with the target analytes in the sample;
- 18 a capture region in said analytical membrane intermediate to said first and second
- ends of said analytical membrane, said capture region being configured to capture labeled
- 20 analytes moving from said first end of said analytical membrane toward said second end of
- said analytical membrane; and
- 22 a backing member between said analytical membrane and said support member to
- facilitate removal of said analytical membrane from said support member for selectively
- 24 reading the assay and archiving said test strip; and
- a magnetic reader device for determining the presence and quantity of magnetic conjugate
- 26 particle labeled target analytes in said capture region, said reader device being shaped and configured
- to receive said test strip after the lateral flow process has been completed.

13. The apparatus recited in claim 12, and further comprising a protective membrane

- 2 covering said analytical membrane on the side opposite to said support member, said protective
- membrane being optically non-transparent.

14. The apparatus recited in claim 13, wherein said protective membrane is formed
2 integrally with said porous membrane.

15. A method for conducting a lateral flow immunoassay quantitative detection of target
2 analytes in a sample, a method comprising:

applying the sample to one end of the porous membrane of a lateral flow test strip;

4 coupling superparamagnetic conjugate particles residing in the test strip at said one end, the
superparamagnetic particles being treated to bind with any target analyte in the sample;

6 capturing the bound complexes of analyte and susperparamagnetic particles in the capture
region of the porous membrane as the sample and bound complexes move through the porous
8 membrane by capillary action;

reading the quantity of labeled analytes in the capture region; and

10 providing an output representative of the quantity of labeled analytes in the capture region.

16. The method recited in claim 15, and further comprising removing the test strip from the
2 lateral flow assay device with the bound complexes remaining available to be selectively stored and
sensed as to the quantity of the bound complexes in the capture region.

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